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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/598,872

05/18/2007

Elan Ziv

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10/12/2010

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EXAMINER

BURK, CATHERINE E

ART UNIT

PAPER NUMBER

3735

MAIL DATE

DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/598,872	Applicant(s) ZIV, ELAN	
	Examiner CATHERINE E. BURK	Art Unit 3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 August 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-37 is/are pending in the application.
- 4a) Of the above claim(s) 23-25,30 and 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-16,18-22,26-29 and 32-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :25 September 2007, 6 August 2008, 22 May 2009, 25 September 2009, 19 January 2010, 5 May 2010, 23 May 2010, 30 May 2010, 28 June 2010, 6 July 2010, 19 July 2010, 29 July 2010, 3 August 2010, 9 August 2010, 16 August 2010, and 16 September 2010.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 1-16, 18-22, 26-29, and 32-37 in the reply filed on August 31st, 2010 is acknowledged.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 35 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
4. Claim 35 recites the limitation "said sizes of said support section and anchoring section" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-11, 13, 14, 16, 18-22, 26-29, 32, and 34-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Kresch (US 5785640 A).
7. Claims 1-5, 14, and 32; Kresch discloses an apparatus sized and shaped for human intra-vaginal insertion. The apparatus is symmetrically arranged around a central axis -17- (claim 14) and comprises a node -4- on the central axis, a support section comprising two supporting arms -

Art Unit: 3735

6- and -8- (claim 4) adapted for providing urethral support and adapted to lie on either side of a urethra (claim 32) (col. 5, lines 1-4 and fig. 6) and an anchoring section comprising two anchoring arms -10- and -12- (claim 5) adapted for resisting movement of the apparatus when in the vagina (col. 4, lines 35-39). The node is preferably about 0.5-1 inches long (col. 4, lines 52-54) and the entire device is preferably 3-5 inches long (col. 6, lines 42-44). Accordingly, the node is less than 30% of the length of the apparatus as a whole (claim 1) and actually may even be less than 20 or 15% of the length of the apparatus (claims 2 and 3).

8. Claims 6 and 7; Kresch discloses a cover -152- (claim 6) that substantially encapsulates all elements of the device (claim 7) to facilitate implantation (fig. 9A).

9. Claims 8 and 9; the entire device is made from flexible material (col. 3, lines 33-37); accordingly, the support section, anchoring section (claim 8) and node (claim 9) are all flexible.

10. Claims 13, 16, and 22; the support section is adapted for providing urethral support using a plurality of outwardly extending arms -6- and -8-. The apparatus further comprises an extending insert -160- which pushes the implant through the cover -152- of an introducer -150- adapted to insert the apparatus into the vagina (claims 13 and 22) (col. 8, lines 35-37). The extending insert urges the arms outwardly by pushing the implant through the introducer, which causes the arms to expand due to their resilient flexible nature. This increases the diameter of the support section (claim 16) (col. 8, lines 46-55).

11. Claim 18; the cover -152- of the introducer, although not disclosed as providing urethral support, is configured to provide urethral support if it were left in the vagina (or during implantation of the implant) and would apply force to the urethra only during an increase in

Art Unit: 3735

abdominal pressure since the implant itself is configured to only provide pressure to the urethra during an increase in abdominal pressure and does not inhibit normal urination (col. 8, lines 1-4).

12. Claim 19; the cover substantially encapsulates both the support section of the implant and the extending insert -160- when the insert has been moved all the way through the lumen of the cover -152- in order to implant the device (col. 8, lines 48-50).

13. Claims 10, 11, 20, and 21; Kresch discloses a device displacer -126- (claims 10 and 20) attached to the support section (claims 11 and 21) (col. 8, lines 21-33).

14. Claim 34; the support section defines a channel -40- (fig. 6) that would allow flowing of vaginal secretions past the apparatus.

15. Claim 35; the length of the apparatus and the sizes of the support and anchoring sections are configured to provide mid-urethral support (fig. 5).

16. Claim 36; the maximal diameter of both the support and anchoring sections is larger than the maximal diameter of the node (fig. 2).

17. Claims 26-29; Kresch discloses a method of treating urinary incontinence comprising providing the apparatus disclosed in the rejection of claim 1, inserting the apparatus into a vagina using an applicator -150- (claim 27) (col. 8, lines 46-48), deploying the apparatus in a position to render mid-urethral support (col. 8, lines 48-55 and fig. 5) (claim 26), and removing the apparatus after a certain period of time (claim 28) (col. 8, lines 4-6) using a device displacer -126- (claim 29) (col. 8, lines 31-33).

18. Claim 37; the method is carried out so as to not cause discomfort to the user (col. 2, lines 51-55) and so as to not block the urethra absent an increase in intra-abdominal pressure (col. 8, lines 1-4)

19. Claims 1, 4, 12, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Gluck (WO 00/67662 A1).

20. Gluck discloses several embodiments of their invention. In this rejection, the embodiment of figs. 11-13 is being relied upon for the rejection of claims 1, 4, and 12 while the embodiment of figs. 15, 16, and 21 is being relied upon for the rejection of claims 1, 4, and 33.

21. Claims 1, 4, and 12; Gluck discloses an apparatus for treating urinary incontinence arranged around a central axis and sized and shaped for human intra-vaginal insertion (fig. 11). The apparatus comprises a support section comprising two arms -46- (claim 4) attached to band -48- and an anchoring section comprising two arms -46- attached to band -50-. Both the support section and the anchoring section are adapted to support the urethra and resist movement of the apparatus once implanted (p. 16, lines 3-5). Bands -48- and -50- are secured around the circumference of a pessary device -2- which results in a bulging of the pessary device between the bands. This bulging area constitutes a node. According to fig. 11, the node occupies less than 1/4 of the length of the whole apparatus; accordingly, the node is not longer than 30% of the length of the apparatus (claim 1). The band -48- constitutes struts interlinking the supporting arms -46- (claim 12).

22. Claims 1, 4, and 33; Gluck discloses an apparatus for treating urinary incontinence arranged around a central axis and sized and shaped for human intra-vaginal insertion (fig. 16). The apparatus comprises a support section and an anchoring section, each labeled as element -116-. Both the support section and the anchoring section are adapted to support the urethra and resist movement of the apparatus once implanted (p. 21, lines 12-15). The area between the two

Art Unit: 3735

sections constitutes a node having a length that is less than 30% of the length of the apparatus as a whole (claim 1) (fig. 16). The support section is provided with a disk -114"- comprising at least four supporting arms (claims 4 and 33) (fig. 21B) used to expand the support section when the apparatus is implanted.

Claim Rejections - 35 USC § 103

23. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

24. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kresch.

25. Kresch discloses the length of the apparatus is preferably about 3-5 inches (col. 6, lines 42-44) which correlates to about 76-127 mm. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to shrink the device disclosed by Kresch to a size of less than 50mm if the patient was quite small or if the device were implanted into a small animal. Furthermore, it has been held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device (In *Gardner v. TEC Systems, Inc.*, 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), cert. denied, 469 U.S. 830, 225 USPQ 232 (1984)).

Conclusion

26. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bartning (US 7717892 B2) discloses an incontinence implant comprising a cover (fig. 8) that supports the urethra; however the priority date of the Bartning patent is later than applicant's priority date.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CATHERINE E. BURK whose telephone number is (571) 270-7130. The examiner can normally be reached on Monday-Thursday 8:30 am - 7:00 pm EDT.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor II can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/C. E. B./
Examiner, Art Unit 3735

/Charles A. Marmor, II/
Supervisory Patent Examiner
Art Unit 3735